JAN 2 3 2003

# 2. 510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

**510(k) Number:** TBD K023114

**Applicant Information:**

| | |
|---|---|
| Date Prepared: | September 11, 2002 |
| Name: | LuMend, Inc. |
| Address: | 400 Chesapeake Drive<br>Redwood City, CA 94063<br>650-364-1400 |
| Contact Person: | Michael A. Daniel |
| Phone Number: | Office: 415-407-0223 |
| Facsimile Number: | (925) 254-5187 |

**Device Information:**

| | |
|---|---|
| Classification: | Class II Percutaneous Catheter |
| Trade Name: | LuMend Frontrunner™ CTO Catheter |
| Common Name: | Percutaneous Catheter |
| Classification Name: | Percutaneous Catheter, 74 DQY / 21 CFR 870.1250 |

**Predicate Devices:**

The LuMend Frontrunner™ CTO Catheter is substantially equivalent in intended use and method of operation to the following predicate device:

LuMend Frontrunner™ CTO Coronary Catheter [K013284]

**Device Description:**

The LuMend Frontrunner™ is a sterile single-use percutaneous catheter consisting of a handle assembly with an integral rotator and a side port for internal device flushing, a proximal braided shaft for push and torque control, a flexible distal shaft which may be manually shaped, and a radiopaque blunt-shaped distal variable-size tip assembly in various shapes and sizes. A handle lever provides manual adjustment of the size of the tip assembly, and the handle rotator provides rotational control for the shaft and distal tip assembly. The distal assembly consists of a set of bilateral hinged tip pieces. The Frontrunner catheter does not have a guide wire lumen.

Guidance and tracking of the catheter through the coronary vasculature is accomplished by selective manual shaping of the flexible distal shaft, and controlled torquing of the handle rotator.

**Intended Use:**

The LuMend Frontrunner™ CTO Catheter is intended to facilitate the intra-luminal placement of conventional guide wires beyond stenotic lesions (including chronic total occlusions) in the peripheral and coronary vasculature prior to further percutaneous intervention.

**Comparison to Predicate Device(s):**

The LuMend Frontrunner™ CTO Catheter is identical to the previously cleared LuMend Frontrunner™ CTO Coronary Catheter in terms of embodiment, shape, appearance and function. It makes use of the identical mechanism of action: "blunt micro-dissection" to facilitate placement of a guide wire across stenotic vascular lesions including Chronic Total Occlusions (CTOs).

***In Vitro, In Situ* and *In Vivo* Test Data:**

LuMend's Quality system, including design control procedures assure that the Frontrunner device continues to meet all appropriate internal and external design input requirements. Routine device evaluation continues to consisted of testing specified in FDA's Coronary and Cerebrovascular Guidewire Guidance Document (January 1995) and included *in vitro* tensile, torque strength, torqueability, tip flexibility, coating adherence/integrity, biocompatibility and catheter compatibility. All data continued to fall well within internal specification requirements, as well as external standard requirements and predicate performance expectations.

**Summary:**

Based upon the product technical information, intended use, performance and biocompatibility information provided in this pre-market notification, the LuMend Frontrunner™ has been shown to be substantially equivalent to a currently marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

LuMend, Inc.
c/o Mr. Michael A. Daniel
Regulatory and Clinical Affairs
400 Chesapeake Drive
Redwood City, CA 94063

SEP 18 2013

Re: K023114
Trade/Device Name: LuMend Frontrunner CTO Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: PDU, DQY
Dated: January 13, 2003
Received: January 14, 2003

Dear Mr. Daniel:

This letter corrects our substantially equivalent letter of January 23, 2003.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

# 4. INDICATIONS FOR USE FORM

**510(k) Number (if known):** K023114

**Device Name:** LuMend ™ Frontrunner CTO Catheter

**Indications For Use:**

The LuMend Frontrunner™ CTO Catheter is intended to facilitate the intra-luminal placement of conventional guide wires beyond stenotic lesions (including chronic total occlusions) in the peripheral and coronary vasculature prior to further percutaneous intervention.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular

510(k) Number K023114